

Serial No.: 10/502,290
Group Art Unit No.: 1651

Amendment to the Claims:

1. (Currently amended): A DNA pharmaceutical agent dosage form, comprising having a dense core element coated with a solid reservoir medium containing the DNA pharmaceutical agent, further comprising a stabilising agent that inhibits the degradative effects of free radicals.

2. (Canceled):

3. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 2 1 wherein the stabilising agent is one or both of a metal ion chelator and a free radical scavenger.

4. (Currently amended): A The A DNA pharmaceutical agent dosage form as claimed in claim 3 wherein the metal ion chelator is selected from the group consisting of: inositol hexaphosphate; tripolyphosphate; succinic and malic acid; ethylenediamine tetraacetic acid (EDTA); tris (hydroxymethyl) amino methane (TRIS); Desferal; diethylenetriaminepentaacetic acid (DTPA); and ethylenediamindihydroxyphenylacetic acid (EDDHA).

5. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 3 wherein the free radical scavenger is selected from the group consisting of ethanol, methionine and glutathione.

6. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1 wherein the stabilising agent that inhibits the degradative effects of free radicals, is a member selected from the group consisting of: Phosphate buffered ethanol solution in combination with methionine or EDTA; and Tris buffered EDTA in combination with methionine or ethanol or a combination of methionine and ethanol.

7. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the solid reservoir medium is an amorphous polyol.

8. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 7, wherein the polyol is a stabilizing polyol.

9. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1 wherein the solid biodegradable reservoir medium is a sugar.

10. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 9 wherein the sugar is a member selected from the group consisting of lactose, glucose, sucrose, raffinose and trehalose.

11. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1 wherein the solid reservoir medium is in the form of a glass.

12. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 11, wherein the solid reservoir medium is in the form of a sugar glass.

13. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the DNA pharmaceutical agent is supercoiled plasmid DNA.

14. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 13, wherein the supercoiled plasmid DNA is stabilized such that after storage at 37°C for 4 weeks greater than 50% of the DNA remains in its supercoiled form.

15. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 13, wherein the DNA is stabilized such that when released the ratio of monomer:dimer supercoiled form is within the range of 0.8:1.2.

16. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the DNA pharmaceutical agent is a vaccine.

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17. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the solid reservoir medium further comprises a member selected from the group consisting of vaccine adjuvant, transfection facilitating agent, DNAase inhibitor and a crystal poisoner.

18. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 17, wherein the vaccine adjuvant is a member selected from the group consisting of CpG, a synthetic imidazoquinoline, tucerasol, a cytokine, MPL, QS21, QS7 and an oil in water emulsion.

19. (Currently amended): A The DNA pharmaceutical agent dosage form, as claimed in claim 1 wherein the dense core element comprises microbeads of a mean particle diameter of between 0.5 to 10 μm .

20. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 19, wherein the microbeads are gold or tungsten microbeads.

21. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 1, comprising making a solution of DNA pharmaceutical agent, reservoir medium, and stabilising agent that inhibits the degradative effects of free radicals in a solvent, followed by coating the at least one dense core element with said solution, and removing the solvent to form a solid reservoir medium containing the pharmaceutical agent and agent that inhibits the degradative effects of free radicals.

22. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 21, wherein the reservoir medium is a sugar.

23. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 22 wherein the concentration of sugar prior to removing the solvent is in the range of 20-40% w/v.

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24. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 23, wherein the solvent is demetalated prior to the process.